K072707 Page 1 of 2

KLS martin L.P.

510(K) SUMMARY

DEC 19 2007

Submitter:	KLS-Martin, L.P. 11239-1 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746 Fax: 904-641-7378
Contact Person:	Jennifer Damato Director RA/QA
Date of Summary:	18 August 2006
Device Name:	Patient Contoured Mesh – PEEK (PCM-P)
Trade Name:	PCM - P
Common Name:	Preformed Plate
Classification Name and Number:	Plate, Cranioplasty, Preformed, Non-Alterable (CFR 882.5330)
Regulatory Class:	II
Predicate Devices:	Patient Contoured Mesh (PCM) (K062570) Stryker Patient Specific Polymer Implant (K043250) Stryker Custom TI Implant (K052871) Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199) Synthes (USA) Patient Specific Cranial/Craniofacial Implant (K033868)
Intended Use:	Patient Contoured Mesh – PEEK (PCM-P) is intended to replace bony voids in the cranial and/or craniofacial skeleton

Device Description:

Patient Contoured Mesh – PEEK (PCM-P) is a custom shaped PEEK panel that is pre-shaped to fit the anatomy of the patient using a CT based model of the patient. Patient Contoured Mesh – PEEK (PCM-P) is fixated using standard KLS Martin's titanium plates and screws in sizes 1.0mm through 2.3mm

Technological Characteristics:

Similarities to Predicate

Patient Contoured Mesh – PEEK (PCM-P), Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199) and Synthes (USA) Patient Specific Cranial/Craniofacial Implant (K033868) are patient specific implants that are manufactured from PEEK.

Differences to Predicate

Patient Contoured Mesh – PEEK (PCM-P) is manufactured from PEEK, the previously cleared Patient Contoured Mesh (PCM) (K062570) is manufactured from titanium and Stryker Patient Specific Polymer Implant (K043250) is manufactured from surgical simplex P radiopaque bone cement.

Substantial Equivalence:

Patient Contoured Mesh – PEEK (PCM-P) is substantially equivalent in intended use and patient specificity to the Patient Contoured Mesh (PCM) (K062570), Stryker Patient Specific Polymer Implant (K043250), Stryker Custom TI Implant (K052871), Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) (K053199) and Synthes (USA) Patient Specific Cranial/Craniofacial Implant (K033868)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2007

KLS-Martin, L.P.
% Ms. Jennifer Damato
Director RAQA
11239-1 St. Johns Industrial Parkway South
Jacksonville, FL 32246

Re: K072707
Trade/Device Name: Patient Contoured Mesh -PEEK (PCM-P)
Regulation Number: 21 CFR 882.5330
Regulation Name: Performed non-alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN, GXP
Dated: November 16, 2007
Received: November 19, 2007

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072707

Device Name: Patient Contoured Mesh – PEEK (PCM-P)

Indications For Use:

Patient Contoured Mesh – PEEK (PCM-P) is intended to replace bony voids in the cranial and/or craniofacial skeleton

Prescription Use ✔ AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carlos Peña

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072707